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510(K) SUMMARY

Submitted by:

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Trade Name: MONARCH™ IOL Delivery System
Common Name: IOL Delivery System
Classification Name: Intraocular lens Guide, 21 CFR 886.4300

1. Predicate Device

The legally marketed device(s) to which we are claiming equivalence to are:

- a. K903574, ChiroFlex Lens Microsert™, (Chiron Ophthalmics Inc.)
- b. K913626, Softrans™ Injector, (STAAR Surgical Company)

2. Device Description

The MONARCH™ IOL Delivery System consists of two parts: an autoclavable, reusable titanium handpiece and a sterile, single-use cartridge. It is a device used for folding and delivering ACRYSOFF® intraocular lenses into the eye for replacement of the human crystalline lens. The system provides a controlled means to reliably place the ACRYSOFF® intraocular lens into the capsular bag.

3. Intended Use of the Device

The intended use of this device is to fold and deliver Alcon ACRYSOFF® intraocular lenses into the eye for replacement of the human crystalline lens.

4. Summary of the Technological Characteristics of the Device

The MONARCH™ IOL Delivery System utilizes a sterile, single use cartridge and a reusable handpiece to deliver ACRYSOFF® lenses. The cartridge is designed for easy loading and reliable folding of ACRYSOFF® lenses. The handpiece accepts the cartridge and delivers the lens by using a plunger to express the lens. The plunger head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by a screw mechanism to ensure a smooth and well controlled lens delivery.

5. Summary of the Performance Data

The performance test demonstrated that the MONARCH™ IOL Delivery System can be used to deliver ACRYSOFF® IOLs without affecting the overall length, haptic angle, power, resolution, or cosmetic attributes of the lenses. The test lenses were delivered smoothly and unfolded completely within 30 seconds in a controlled fashion.

6. Conclusions

The MONARCH™ IOL Delivery System is easy to use, properly delivers the Alcon ACRYSOFF® intraocular lens, and is substantially equivalent to devices such as the Softrans™ Injector (Model ET) or the ChiroFlex Lens Microsert™ system.